

PSJ3

Exhibit 434

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From: Bennett, Pamela (Gov't Affairs)
Sent: Tue 4/12/2016 9:55:00 PM
Subject: Fwd: S. 483 (Ensuring Patient Access and Effective Drug Enforcement Act)

Pamela Bennett, RN, BSN, CCE
Cell: [REDACTED]

Begin forwarded message:

From: "Rosen, Burt" <Burt.Rosen@pharma.com>
Date: April 12, 2016 at 7:03:28 PM CDT
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Subject: S. 483 (Ensuring Patient Access and Effective Drug Enforcement Act)

This evening the House passed S. 483 (Ensuring Patient Access and Effective Drug Enforcement Act) which had previously passed the Senate. The bill will now be sent to the President for his signature. He is expected to sign the bill as all controversy has been resolved.

The bill is one we have been working on with HDMA and NACDS for the past two years. The bill is designed to clarify when DEA can take action against a registrant, and allows for notice to the registrant with the opportunity to take corrective action prior to DEA revoking or suspending a registrant's license. Purdue was very active in influencing the ultimate definition of an "imminent danger to the public health or safety".

Below is a summary of the legislation.

Ensuring Patient Access and Effective Drug Enforcement Act

Amends the Controlled Substances Act to define: (1) "factors as may be relevant to and consistent with the public health and safety," for purposes of the Attorney General's determination of whether registering an applicant to manufacture or distribute a controlled substance in schedule I or II is in the public interest, as factors that are relevant to and consistent with the findings of such Act; and (2) "imminent danger to the public health or safety," for purposes of the suspension of such a registration, to mean that in the absence of an immediate suspension order, controlled substances will continue to be distributed or dispensed by a registrant who knows or should know, through fulfilling the obligations of the registrant under such Act, that the dispensing is outside the usual course of professional practice, that the distribution or dispensing poses a present or foreseeable risk of adverse health consequences or death due to the abuse or misuse of the controlled substances, or that the controlled substances will continue to be diverted outside of legitimate distribution channels.

Requires an order to show cause as to why such a registration should not be denied, revoked, or suspended to: (1) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated; (2) direct the applicant or registrant to appear before the Attorney General at a specific place and time within 30 days after receipt of the order; and (3) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before such appearance. Requires the Attorney General, upon review of any such plan, to determine whether denial, revocation, or suspension proceedings should be discontinued or deferred for purposes of modifications to such plan. Makes such requirements inapplicable to the issuance of an immediate suspension order.

Directs the Department of Health and Human Services, acting through the Food and Drug Administration and the Centers for Disease Control and Prevention, to submit a report identifying: (1) obstacles to legitimate patient access to controlled substances; (2) issues with diversion of controlled substances; and (3) how collaboration between federal, state, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances.